

September 2004



Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

3380 Americana Terr, Suite 320, Boise, ID 83706

Board Members

Mike Merrill, RPh, from Idaho Falls has been reappointed to the Idaho Board of Pharmacy by Governor Dirk Kempthorne for another five-year term. At the June Board meeting Frank Casabonne, RPh, from Boise was elected chairman of the Board and Dwayne Sheffler, RPh, from Sandpoint was elected vice chairman. Other members of the Board include Marilyn Silcock, PhD, of Pocatello and Kitty Gurnsey public member, from Boise.

Controlled Substance Tracking Program

In October 2003, the Idaho Board of Pharmacy was awarded a grant from the Department of Justice, which was to be used to enhance our existing Controlled Substance Prescription Monitoring Program. We have now developed a program allowing the Board to receive prescription data directly from pharmacies that were previously collected by an outside vendor, Atlantic Associates. The prescription information is to be transmitted via disk, CD-ROM, e-mail (no zip files), or FTP. The only form of transmission we are not able to accept is via modem.

There is no change in the data required or the date of submission. Information is still required for all prescriptions filled for Schedules II, III, and IV. Pharmacies are required to report this information by the first of the month for the previous month's prescriptions.

If you have not been contacted by your software vendor or the Board of Pharmacy with instructions on the submission process, please contact Teresa Anderson at the Board of Pharmacy (208/334-2356).

Medicaid Prior Authorization of Long-Acting Opioids

Idaho Medicaid will be adding long-acting opioids to its Enhanced Prior Authorization Program (EPAP) on October 1, 2004. Methadone, Avinza®, and Kadian® will be considered preferred agents and will not require prior authorization. The other agents (see table) will require prior authorization for non-cancer patients. Physicians and pharmacists are encouraged to work together over the next 60 days to transition all non-cancer pain patients from non-preferred to preferred agents. For assistance please refer to the education document "Oral Opioids for Chronic Non-Malignant Pain" available in the August *DUR Discovery* newsletter. Idaho Medicaid prior authorization criteria are located on the Medicaid Pharmacy Web site, www.idahohealth.org.

Long-Acting Opioids Preferred Agents

Avinza
Kadian
Methadone

Long-Acting Opioids Non-Preferred Agents

Duragesic® system*
Morphine sulfate long-acting
MS Contin®
Oramorph SR™
Oxycodone HCL long-acting
OxyContin®

**Duragesic system will be approved for clients >65 years old without further prior authorization requirements.*

Medicaid Information Release MA04-32

TO: Pharmacies, Nursing Facilities, and Residential or Assisted Living Facilities
FROM: Kathleen Allyn, Deputy Administrator
SUBJECT: RETURNED DRUG FEE PROCESS

Effective 7/1/04 pharmacies will be able to receive a returned drug fee of \$6.00 each time they accept the return of unused medication from an Idaho Medicaid prescription (IDAPA 16.03.09. 817.07). This fee only applies to unused medications returned by either a Nursing Facility or a Residential or Assisted Living Facility. To qualify for the fee, the value of the unused medication returned from each prescription must equal \$15.00 or more and must be for dates of service on or after 7/1/04. Continue to process claims adjustments for these returns using existing procedures.

To request the returned drug fee from the Department, the pharmacy must complete a Returned Drug Fee Request Form.

To access an electronic (Excel spreadsheet) version of this form go to: www2.state.id.us/dhw/Medicaid and click on Information for Providers. Then click on Medicaid Information Releases and click on 2004 Information Releases. Look for MA04-32 in the Number column. In the Subject column click on the Returned Drug Fee Request Form and it will take you to the [Microsoft] Excel® version of the form.

To receive a paper copy by fax or mail, call 208/364-1994.



National Pharmacy Compliance

(Applicability of the contents of articles in the National Pharmacy Compliance and can only be ascertained by examining the original article.)

FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: isminfo@ismp.org.



According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of



Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- ◆ If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- ◆ Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- ◆ Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- ◆ Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- ◆ Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- ◆ Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- ◆ Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

Medication Return Requirements

If your pharmacy is servicing assisted living and/or long-term care facilities please refer to our June 2004 *Newsletter*, which covers the changes to Board Rule 156 on the requirements for the return of medication from these facilities.

Pharmacy Technicians

The governor's office has approved a temporary rule that increases the technician to pharmacist ratio to 3:1. This ratio change is now in effect and you may use three (3) registered technicians to every one (1) licensed pharmacist. This pertains to both retail and hospital pharmacies. This in no way affects the intern/extern ratio of 1:1.

The Board interpretation of clerk, cashier, and technician duties has not changed from the April 2004 clarification and must be in place in your pharmacies now to meet compliance standards.

With the new clarification of duties and the ratio increase for registered technicians, it is imperative that the inspectors be able to identify all personnel working in the pharmacy. Name badges must be worn by technicians at all times and the pharmacist-in-charge is responsible for making sure that each technician is wearing his or her name badge and properly identifying himself or herself when answering the phone.

The following is the interpretation of duties that may be performed by pharmacy personnel not licensed or registered as interpreted by the Board and its attorney.

1. Delivery of medications to the patients' residence.
2. Adjudicate claims for previously dispensed medications and handle billing questions. When filling a prescription only a pharmacist or registered technician may handle insurance or third party transactions connected with the processing of that prescription.
3. Stock shelves in the pharmacy.
4. Answer the phone. All calls dealing with a prescription must then be immediately directed to a licensed pharmacist or registered technician. No refills or prescription information may be handled by a clerk/cashier.
5. A licensed pharmacist or registered technician must do the initial transfer or handing of a prescription to the patient at the pharmacy.
6. A cashier/clerk may only ring up a prescription after the registered technician or licensed pharmacist has completed the initial transaction with the patient.

7. A cashier/clerk may not hand a prescription to a patient at a pharmacy's drive-up window. Only a licensed pharmacist or registered technician can complete the initial transfer or handing of the prescription to the patient.

All technicians, clerks, and cashiers must wear name badges for identification purposes. Technicians working in the capacity as a clerk/cashier must identify themselves as such with a name badge. If not identified, Board of Pharmacy inspectors will assume they are performing as a technician without a name badge and they will be cited.

Borrowing Leads to Sorrowing

An issue that compliance officers routinely address is the issue of **borrowing** controlled substances from another pharmacy. We have had multiple instances where audits did not come out properly and where countless hours were spent tracking down the problem. In several of these instances the error was traced back to a **borrowing** incident. If you run short of a Schedule II substance, take out your 222 Forms and purchase it in the proper manner from the other pharmacy. If you run short of a Schedule III-V product have the selling pharmacy create an invoice, make sure you receive a copy of that invoice, and both pharmacies must then file that copy with their other controlled substance invoices, verifying the disbursement or receipt of a controlled substance.

Consumer Credit Requires Notice

The Idaho Department of Finance wants you to know that you must notify that agency if you extend, arrange, or take assignment of consumer credit. "Consumer credit" means the transaction is for personal, family, or household purposes.

To find out if this applies to you, or to request a notification form, contact the Idaho Department of Finance, Consumer Finance Bureau, at 208/332-8002, or by visiting www.idahofinance.com.

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National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60068
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